



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

May 31, 2005

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 71654-7, Virkon
DP Barcode: 315367

From: Tajah L. Blackburn, Ph.D., Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

[Handwritten signature] 6/6/05

Thru: Nancy Whyte, Acting Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

[Handwritten signature]
June 7, 2005

To: Adam Heyward PM 34/ Stacey Grigsby
Regulatory Management Branch II
Antimicrobials Division (7510C)

Applicant: E.I. Du Pont de Nemours and Company
1007 Market Street
Wilmington, DE 19898

Formulation from Label

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Potassium peroxymonosulfate.....	21.41%
Sodium chloride	1.50%
<u>Other Ingredient(s)</u>	<u>77.09%</u>
Total	100.00%

I BACKGROUND

The product, Virkon (EPA Reg. No. 71654-7), is an EPA-registered "one-step" disinfectant (bactericide, fungicide, virucide) for use on hard, non-porous surfaces in household, institutional, commercial, food processing, and hospital/medical environments. The applicant requested to amend the registration of this product to add claims for effectiveness as a disinfectant against *Staphylococcus aureus* (MRSA), *Enterococcus faecalis* (VRE), *Escherichia coli* O157:H7, Norwalk virus, Respiratory syncytial virus, and Influenza A virus. The applicant also requested to add claims for effectiveness as a sanitizer for non-food contact surfaces. Studies were conducted at MicroBioTest, Inc., located at 105B Carpenter Drive in Sterling, VA 20164; and ATS Labs, located at 1285 Corporate Center Drive, Suite 110 in Eagan, MN 55121.

This data package contained a letter from the applicant to EPA (dated March 14, 2005), EPA Form 8570-1 (Application for Pesticide), eight studies (MRID Nos. 464986-01 through 464986-08), Statements of No Data Confidentiality Claims for all eight studies, and the proposed label.

Note: The laboratory reports describe studies conducted for the product, Virkon S. The applicant's letter to EPA (dated March 14, 2005) states that the products, Virkon S (EPA Reg. No. 71654-6), and the product, Virkon (EPA Reg. No. 71654-7) are identical; "historically separate registration have been maintained since the two products are typically sold into different applications."

II USE DIRECTIONS

Disinfection Directions

The product is designed for disinfecting hard, non-porous surfaces such as respirators and manikins used in CPR training. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Remove gross dirt. Prepare a use solution by adding 1 tablet of the product to 1 pint of water (a 1% dilution). Apply use solution using a sponge, brush, or sprayer. Allow surfaces to remain wet for 10 minutes. Air dry. A potable rinse is required for food contact surfaces.

Sanitization Directions

The product also may be used to sanitize manikins used in CPR training. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizer: Prepare a use solution by adding 3 tablets of the product to 1 pint of water (a 3% dilution). Apply use solution using a sprayer or saturated cloth. Allow surfaces to remain wet for 30 seconds. Wipe dry and rinse with potable water.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are also presented in DIS/TSS-1.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Virucides - Novel Virus Protocol Standards

To ensure that newer virus protocols have been adequately validated (e.g., a method for Feline calicivirus), data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory).

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. Testing requirements in EPA DIS/TSS-10 may be used. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an

appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID No. 464986-01 "H-26819 and H-26820: Use Dilution Test Supplemental Microorganism (*Staphylococcus aureus*, MRSA, ATCC 33592)" for Virkon S, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date— March 7, 2005. Laboratory Project Identification Number 473-108.

This study was conducted against *Staphylococcus aureus* (MRSA) (ATCC 33592). Two lots (Lot Nos. 5471 and 19861) of the product, Virkon S (also identified as H-26819 and H-26820), were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A 1% use solution was prepared using 400 ppm AOAC synthetic hard water (titration results not provided). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 20 carriers per 20 ml broth. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was exposed to 10 ml of the use solution for 10 minutes at 19°C. The carriers were transferred to tubes of Lethen broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included those for sterility, viability, neutralizer effectiveness/toxicity, dried carrier counts, bacteriostasis, antibiotic resistance, and confirmation of the challenge microorganism.

Note: Antibiotic resistance of *S. aureus* (MRSA) was verified on a representative culture. The measured zone of inhibition confirmed resistance of *S. aureus* to oxacillin.

2. MRID 464986-02 "H-26819 and H-26820: Use Dilution Test Supplemental Microorganism (*Enterococcus faecalis*, VRE, ATCC 51299)" for Virkon S, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – March 7, 2005. Laboratory Project Identification Number 473-109.

This study was conducted against *Enterococcus faecalis* VRE (ATCC 51299). Two lots (Lot Nos. 5471 and 19861) of the product, Virkon S (also identified as H-26819 and H-26820), were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A 1% use solution was prepared using 400 ppm AOAC synthetic hard water (titration results not provided). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 20 carriers per 20 ml broth. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was exposed to 10 ml of the use solution for 10 minutes at 19°C. The carriers were transferred to tubes of Lethen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included those for sterility, viability, neutralizer effectiveness/toxicity, bacteriostasis, antibiotic resistance, dried carrier counts, and confirmation of the challenge microorganism.

Note: The study was conducted according to GLP standards with the following exception: The neutralizer effectiveness control tube result was not documented on the day evaluated.

Note: Antibiotic resistance of *Enterococcus faecalis* VRE was verified on a representative culture. The measured zone of inhibition confirmed antibiotic resistance of *Enterococcus faecalis* VRE to vancomycin.

3. MRID 464986-03 "H-26819, H-26820, and H-26836: Sanitizer Test for Non-Food Contact Surfaces" for Virkon S, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Amended report date – March 14, 2005. Final report date – March 7, 2005. Laboratory Project Identification Number 473-110.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. 5471, 19861, and 17370) of the product, Virkon S (also identified as H-26819, H-26820, and H-26836), were tested using a MicroBioTest protocol titled "Sanitizer Test for Non-Food Contact Surfaces," dated December 29, 2004 (copy provided). All three product lots tested were at least 60 days old at the time of testing. A 3% use solution was prepared using 400±2.9% ppm AOAC synthetic hard water (titration results not provided). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Three, 1 x 1 inch glass slide carriers per product lot per microorganism were inoculated with 0.01-0.03 ml of a 18-24 hour old suspension of the test organism. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was exposed to 5 ml of the use solution for 30 seconds at 23°C. Excess liquid was allowed to drain. The carriers were transferred to 20 mL of stripping fluid containing 0.1% sodium thiosulfate to neutralize. The test suspensions were serially diluted ten-fold in phosphate buffer saline dilution blanks and plated in duplicate in nutrient agar plates. All subcultures were incubated for 48±2 hours at 37±2°C, and the colonies

were calculated. Controls included those for zero time control, neutralizer effectiveness, parallel counts, sterility, and confirmation of the challenge microorganisms.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

4. MRID 464986-04 "H-26819 and H-26820: Use Dilution Test (*Escherichia coli* O157:H7, ATCC 43895)" for Virkon S, by Angela L. Hollingsworth. Study conducted at MicroBioTest, Inc. Study completion date – March 7, 2005. Laboratory Project Identification Number 473-111.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43895). Two lots (Lot Nos. 5471 and 19861) of the product, Virkon S (also identified as H-26819 and H-26820), were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 16th Edition, 1995. A 1% use solution was prepared using 400 ppm AOAC synthetic hard water (titration results not provided). Heat-inactivated horse serum was added to the culture to achieve a 5% organic soil load. Ten (10) stainless steel penicylinder carriers were immersed in a 48-54 hour old suspension of the test organism, at a ratio of 20 carriers per 20 ml broth. The carriers were dried for 20-40 minutes at 37±2°C. Each carrier was exposed to 10 ml of the use solution for 10 minutes at 19°C. The carriers were transferred to tubes of Lethen Broth containing 0.1% sodium thiosulfate to neutralize. All subcultures were incubated for 48±2 hours at 37±2°C, and then examined for the presence or absence of visible growth. Controls included those for sterility, viability, neutralizer effectiveness/toxicity, bacteriostasis, dried carrier counts, and confirmation of the challenge microorganism

5. MRID 464986-05 "H-26819: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces – Confirmatory Assay (Feline Calicivirus as a surrogate for Norwalk and Norovirus)" for Virkon S, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 7, 2005. Project Number A02683.

This study, under the direction of Study Director Mary J. Miller, was conducted against Feline calicivirus (F-9 Strain; ATCC VR-782) using Crandel Reese feline kidney cells (CRFK cells; ATCC CCL-94; originally obtained from ATCC; propagated in-house) as the host system. The study protocol followed ATS Labs Protocol No. DUP01122904.FCAL.2 (copy not provided). One lot (Lot No. 5471) of the product, Virkon S (also identified as H-26819), was tested. A 1% use solution was prepared using 400 ppm AOAC synthetic hard water (titrated at 400 ppm). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Two glass carriers were tested for the single product lot against the target virus. Films of virus were made by spreading 0.2 ml of stock virus on the bottoms of separate sterilized Petri dishes. The virus films were air-dried for 20 minutes at 20.1°C in 65% relative humidity. For the single product lot, 2.0 ml of the use solution was added to the virus films for 10 minutes at 20.1°C. After the contact period, the virus-disinfectant mixture was scraped from the surface of the dish with a cell scraper. Each sample (2.0 ml) was passed through Sephadex columns to neutralize. A 0.2 ml aliquot of the virus film was resuspended in 2.0 ml of the use solution (a 1:10 dilution). Ten-fold serial dilutions were prepared, using Minimum Essential Medium containing 5% (v/v) heat-

inactivated fetal bovine serum, 0.01 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of each dilution and incubated at 31-35°C in a humidified atmosphere of 5-7% CO₂. The cultures were microscopically scored for 7 days for the presence or absence of cytopathic effects (i.e., small, rounding of cells with a slight granular look), cytotoxicity, and viability. Controls included those for input virus count, dried virus count, neutralization, and cytotoxicity. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The Most Probably Number (MPN) was determined using the EPA approved method (January 4, 2001).

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

6. MRID 464986-06 "H-26819 and H-26820: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces (Feline Calicivirus as a surrogate for Norwalk and Norovirus)" for Virkon S, by Karen M. Ramm. Study conducted at ATS Labs. Study completion date – March 7, 2005. Project Number A02684.

This study, under the direction of Study Director Karen M. Ramm, was conducted against Feline calicivirus (F-9 Strain; ATCC VR-782) using Crandel Reese feline kidney cells (CRFK cells; ATCC CCL-94; obtained from ATCC; propagated in-house) as the host system. The study protocol followed ATS Labs Protocol No. DUP01122904.FCAL.1 (copy provided). Two lots (Lot Nos. 5471 and 19861) of the product, Virkon S (also identified as H-26819 and H-26820), were tested. A 1% use solution was prepared using 400 ppm AOAC synthetic hard water (titrated at 408 ppm). The stock virus culture contained 5% fetal bovine serum as the organic soil load. Two glass carriers were tested for each product lot against the target virus. Films of virus were made by spreading 0.2 ml of stock virus on the bottoms of separate sterilized glass Petri dishes. The virus films were dried for 20 minutes at 20.1°C in 50-65% relative humidity. For each lot of product, 2.0 ml of the use solution was added to the virus films for 10 minutes at 20.1°C. After the contact period, the virus-disinfectant mixture was scraped from the surface of the dish with a cell scraper. Each sample (2.0 ml) was passed through Sephadex columns to neutralize. A 0.2 ml aliquot of the virus film was resuspended in 2.0 ml of the use solution (a 1:10 dilution). Ten-fold serial dilutions were prepared, using Minimum Essential Media containing 5% (v/v) heat-inactivated fetal bovine serum, 0.01 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of each dilution and incubated at 31-35°C in a humidified atmosphere of 5-7% CO₂. The cultures were microscopically scored for 7 days for the presence or absence of cytopathic effects (i.e., small, rounding of cells with a slight granular look), cytotoxicity, and viability. Controls included those for input virus count, dried virus count, neutralization, and cytotoxicity. Viral and cytotoxicity titers were calculated by the method of Spearman Karber. The Most Probably Number (MPN) was determined using the EPA approved method (January 4, 2001).

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

7. MRID 464986-07 "H-26819 and H-26820: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces (Respiratory syncytial virus)" for Virkon S, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 7, 2005. Project Number A02682.

This study was conducted against Respiratory syncytial virus (Strain Long, ATCC VR-26), using Hep-2 cells (human larynx carcinoma; propagated in-house; originally obtained from ATCC; ATCC CCL-23) as the host system. Two lots (Lot Nos. 5471 and 19861) of the product, Virkon S (also identified as H-26819 and H-26820), were tested according to ATS Labs Protocol No. DUP01122804.RSV (copy not provided). A 1% use solution was prepared using 400 ppm AOAC synthetic hard water (titrated at 404 ppm). The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 14.9°C in a relative humidity of 51% for 20 minutes. For each lot of product, separate dried virus films were treated with 2.0 ml of the use solution. The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 minutes at 21°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and diluted serially in Minimum Essential Medium supplemented with 2% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 10 units/ml penicillin, 1.0 mM L-glutamine, and 2.5 µg/ml amphotericin B. Hep-2 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂ and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus count, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

8. MRID 464986-08 "H-26819 and H-26820: Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces (Influenza A virus)" for Virkon S, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – March 7, 2005. Project Number A02681.

This study was conducted against Influenza A virus (Strain Hong Kong, ATCC VR-544), using RMK cells (Rhesus monkey kidney cells; obtained from ViroMed Laboratories, Inc.) as the host system. Two lots (Lot Nos. 5471 and 19861) of the product, Virkon S (also identified as H-26819 and H-26820), were tested according to ATS Labs Protocol No. DUP01122804.FLUA (copy not provided). A 1% use solution was prepared using 400 ppm AOAC synthetic hard water (titrated at 404 ppm). The stock virus culture was adjusted to contain a 5% organic soil load (fetal bovine serum). Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried at 20.0-20.1°C at 50% relative humidity for 20 minutes. For each lot of product, separate dried virus films were treated with 2.0 ml of the use solution. The virus films were completely covered with the use solution, and remained exposed to the use solution for 10 minutes at 20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixture was passed through a Sephadex column, and

diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO₂ and scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for cytotoxicity, dried virus controls, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V RESULTS

MRID No	Organism	No. Exhibiting Growth/Total No. Tested		Dried Carrier Count (CFU/carrier)
		Lot No. 5471	Lot No. 19861	
464986-01	<i>Staphylococcus aureus</i> MRSA	0/10	0/10	1.0 x 10 ⁵
464986-02	<i>Enterococcus faecalis</i> VRE	0/10	0/10	2.1 x 10 ⁴
464986-04	<i>Escherichia coli</i> O157:H7	0/10	0/10	5.3 x 10 ⁴

MRID No.	Organism	Results			Dried Virus Control (TCID ₅₀ /0.1 ml)
			Lot No. 5471	Lot No. 19861	
464986-07	Respiratory syncytial virus	10 ⁻¹ to 10 ⁻⁷ dilutions	Complete inactivation	Complete inactivation	10 ^{4.5}
		TCID ₅₀ /0.1 ml	≤10 ^{0.5}	≤10 ^{0.5}	
464986-08	Influenza A virus	10 ⁻¹ to 10 ⁻⁸ dilutions	Complete inactivation	Complete inactivation	10 ^{6.0}
		TCID ₅₀ /0.1 ml	≤10 ^{0.5}	≤10 ^{0.5}	

MRID No.	Organism	Mean of Duplicates expressed in Log ₁₀ MPN/ml		
		Lot No. 5471	Lot No. 19861	Dried Virus Control
464986-06	Feline calicivirus	0.00 Complete inactivation	0.00 Complete inactivation	5.37983, 5.20316
464986-05	Feline calicivirus	0.00 Complete inactivation	0.00 Complete inactivation	5.55827, 5.79356

MRID No.	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent reduction
			(CFU/carrier)		
464986-03	<i>Klebsiella pneumoniae</i>	5471	<1.0 x 10 ¹	1.7 x 10 ⁴	>99.9
		19861	<1.0 x 10 ¹		>99.9
		17370	<1.0 x 10 ¹		>99.9
464986-03	<i>Staphylococcus aureus</i>	5471	<1.0 x 10 ¹	7.9 x 10 ⁴	>99.9
		19861	<1.0 x 10 ¹		>99.9
		17370	<1.0 x 10 ¹		>99.9

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Virkon, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1% dilution:

Staphylococcus aureus (MRSA)
Enterococcus faecalis (VRE)
Escherichia coli O157:H7

MRID No. 464986-01
MRID No. 464986-02
MRID No. 464986-04

Complete inactivation (no growth) was observed in all subcultures tested against the required number of product lots (i.e., two). Dried carrier counts were at least 10⁴. Neutralizer effectiveness testing showed positive growth of the microorganisms. Viability controls were positive for growth. Sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, Virkon, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 1% dilution:

Respiratory syncytial virus
Influenza A virus

MRID No. 464986-07
MRID No. 464986-08

Complete inactivation (no growth) was indicated in all dilutions tested. Cytotoxicity was not observed. Recoverable virus titers of at 10^4 were achieved.

3. The submitted efficacy data (MRID Nos. 464986-05 and -06) support the use of the product, Virkon, as a disinfectant with virucidal activity against **Feline calicivirus** (a surrogate for Norovirus) on hard, non-porous surfaces in the presence of 400 ppm hard water and a 5% organic soil for a contact time of 10 minutes at a 1% dilution. Complete inactivation (no growth) was indicated in the 10⁻¹ through 10⁻⁴ dilutions. No cytotoxicity was observed. Recoverable virus titers of at least 10⁴ was achieved. The studies were performed at the same laboratory but under the direction of different study directors. Both studies used two carriers per lot of product. The confirmatory study used one lot of product.

4. The submitted efficacy data (MRID No. 464986-03) support the use of the product, Virkon, as a sanitizer against ***Klebsiella pneumoniae*** and ***Staphylococcus aureus*** on non-food contact surfaces in the presence of 400 ppm hard water and a 5% organic soil load for a contact time of 30 seconds at a 3% dilution. A 99.9% reduction in population was observed. Neutralizer effectiveness testing showed positive growth of the microorganisms. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of Virkon as a disinfectant on hard, non-porous surfaces against the following microorganisms, in the presence of a 5% organic soil load for a contact time of 10 minutes at a 1% dilution:

Enterococcus faecalis (VRE)
Escherichia coli O157:H7
Staphylococcus aureus (MRSA)
Influenza A virus
Respiratory syncytial virus
Norovirus* (see Recommendation #5)

The submitted efficacy data provided by the applicant support these claims.

2. The proposed label claims are acceptable regarding the use of Virkon as a sanitizer on non-food contact surfaces for a contact time of 30 seconds when diluted 3%, in the presence of a

5% organic soil load. Data provided by the applicant support this claim.

3. The following new claim has been added to the product label [see pages 3 and 7 of the proposed label]: "A 1% solution is effective for 5 days; 2 or 3% solutions should be made fresh daily." This claims should be removed from the label, until efficacy data is submitted.

4. According to the Centers for Disease Control and Prevention, Norovirus was recently approved as the official name for the group of viruses provisionally described as "Norwalk-like viruses" (NLV)¹. In an effort to be current and accurate, the proposed label must be changed to reflect current nomenclature.

*5. On the proposed label, "*Campylobacter pyloridis*" should be changed to "*Helicobacter pylori*", as this is consistent with current nomenclature.

6. On page 2 of the proposed label, the "If Inhaled" section has been removed. Please provide rationale for the removal of this First Aid statement.

7. On page 9 of the proposed label, "*E. coli* O157" should be changed to "*E. coli* O157:H7".

8. On page 10 of the proposed label, all references to "most surfaces" should be changed to "most hard, non-porous surfaces".

1. <http://www.cdc.gov/ncidod/dvrd/revb/gastro/norovirus-factsheet.htm>